Remarks and Arguments

Claims 1-10 are pending in this application. Claims 1 and 4 have been amended to more particularly point out the invention. Support for the amendments can be found throughout the specification, e.g. page 4, lines 5-17; page 14, lines 18-22; page 26, lines 35-38; page 34, lines 11-25; page 29, lines 20-26.. Claims 5 and 8 have been canceled without prejudice.

Applicants gratefully acknowledge that the claims have been found to be free of the art.

I. Claim Objections

Claim 1 is objected to because the Office believes that cells do not differentiate into areas. In order to expedite prosecution Applicants have amended claim 1 to recite "cells" instead of areas. Applicants believe the amendment obviates the objection.

II. 35 U.S.C. § 112 1st Paragraph

A. New Matter

Applicants gratefully acknowledge withdrawal of the new matter rejection

B. Enablement

Claims 1-10 stand rejected as allegedly not enabled. The Office admits that the claims are enabled for a method of generating cardiomyocytes and cardiomyocyte precursor cells from hES cells obtained from a human blastocyst comprising initiating differentiation of the hES by forming embryoid bodies (EB) in suspension culture wherein some of the hES cells of the EB differentiate into cells that undergo spontaneous contraction, harvesting the differentiated cells that undergo spontaneous contraction, separating the harvested cells into fractions by gradient density centrifugation, collecting the fractions with a density of between ~1.05 and `1.075 g/ml and isolating the cells from the collected fractions that express cardiac troponin I, cardiac

troponin, atrial natriurectic factor or α-cardiac myosin heavy chain thereby generating a cell composition comprising cardiomyocytes and cardiomyocytes precursors. Moreover, the Office admits that the method is enabled wherein initiating differentiation occurs in a growth environment comprising serum, activin, insulin like growth factor and TGFβ. However, the Office believes that the claims are not enabled for 1) a method of generating cardiomyocytes comprising collecting any fraction of a density gradient; 2) a method of generating cardiomyocytes comprising differentiating hES cells in a growth environment comprising any morphogen and any growth factors and without serum; and 3) a method of generating a cell composition containing cardiomyocytes or cardiomyocyte precursor cells only. Applicants address each of these concerns in turn.

1. The Legal Standard

A disclosure enables a claim if it contains sufficient information such that a skilled artisan in the pertinent art can make and use the claimed invention without undue experimentation. *In re Wands* 8 USPQ 2d 1400 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation *In re Certain Limited-Charge Cell Culture Microcarriers* 221 USPQ 1165 (Int'l Trade Comm'n 1983). As long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. *In re Fisher* 166 USPQ 18, 24 (CCPA 1970).

2. Cardiomyocytes Collected From Any Fraction of a Density Gradient

Applicants believe the claims are enabled for collecting cardiomyocytes from any fraction of a density gradient. Applicants first note that two working examples (Example 2 and

Example 9) are provided in the specification demonstrating the collection of cardiomyocytes from a density gradient. In Example 2 cells were isolated from the top of the gradient and the interface of the two layers. Both fractions contained cardiomyocyte like cells as measured by markers and physiological phenotype. Moreover, in Example 9 cells were isolated from the top of the gradient, the interface of the gradient, and from within each respective fraction of the gradient. Nonetheless, while disagreeing with the rejection and solely for the purpose of expediting prosecution, Applicants have amended claim 1 to recite a "density wherein the cells are present in the fraction having a density of about 1.05 g/ml, a fraction having a density of about 1.075 g/ml, a fraction including an upper interface of a gradient comprising a fraction having a density of about 1.05 g/ml, and a fraction having a density of about 1.075 g/ml, and a fraction including a lower interface of a gradient comprising a fraction having a density of about 1.05 g/ml, and a fraction having a density of about 1.075 g/ml." Applicants believe the amendment obviates the rejection.

3. Growth Factors Morphogen and Serum Free Growth Conditions

The Office believes that the claims are not enabled for any growth factors or any morphogens. Without acquiescing in the rejection and for sole purpose of expediting prosecution, Applicants have amended claim 4 to recite: a growth environment comprising activin, an insulin-like growth factor and a member of the TGFβ family. Applicants believe this amendment obviates the rejection.

Turning to the Office's concern regarding the necessity for serum in the differentiation media, while disagreeing with the rejection and for the sole purpose of expediting prosecution, Applicants have amended claim 1 to recite a media comprising serum. Applicants believe the amendment obviates the rejection.

4. Cardiomyocytes or Cardiomyocyte Precursor Cells Only

The Office believes the claims are not enabled for a cell composition of cardiomyocytes or cardiomyocyte precursor cells only. While not acquiescing in the rejection, and for the sole purpose of expediting prosecution, Applicants have amended claim 1 to recite cells of cardiomyocyte lineage. Applicants believe the amendment obviates the rejection.

III. 35 U.S.C. § 112 2nd Paragraph

Applicants gratefully acknowledge withdrawal of the indefiniteness rejection.

III. Double Patenting

Claims 1, 2, 6-8 stand provisionally rejected as allegedly unpatentable over claims 1-13, 15 and 16 of co-pending Application No. 11/085,899. Applicants note that Application No. 11/085,899 has been **abandoned** and thus request withdrawal of this rejection.

Claims 1, 2, 4, 7, 8 stand provisionally rejected as allegedly unpatentable over claims 1-5 and 8-12 of co-pending Application No. 11/086,709 on the ground of non-statutory obviousness-type double patenting. Applicants request that this rejection be held in abeyance until there is allowable subject matter in this case.

Claims 1-5, 7, 8 and 10 stand provisionally rejected as allegedly unpatentable over claims 1-10 and 12-18 of co-pending Application No. 11/040691on the ground of non-statutory obviousness-type double patenting. Applicants request that this rejection be held in abeyance until there is allowable subject matter in this case.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this filing and charge any additional required fees to our deposit account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

E. Stewart Mittler
Reg. No. 50,316

March 4, 2008

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Telephone: (650) 566-7237
Fax: (650) 473-8654